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and Eye Therapies, LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE LUMIFY	Civil Action No. 21-16766 (RK) (RLS) (CONSOLIDATED) *Document Electronically Filed* **COUNSELS' EYES ONLY – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT, TRADEMARK INFRINGEMENT, TRADE DRESS INFRINGEMENT, COPYRIGHT INFRINGEMENT, AND UNFAIR COMPETITION

Plaintiffs Bausch & Lomb, Inc., ("Bausch"), Bausch & Lomb Ireland Limited, and Eye Therapies, LLC (collectively, "Plaintiffs") by way of this First Amended Complaint against Defendants Slayback Pharma LLC, Slayback Pharma India LLP, Dr. Reddy's Laboratories S.A., and Dr. Reddy's Laboratories, Inc., (collectively, "Defendants"), amending the Complaint filed in Civil Action No. 23-22906 (which was consolidated into the above-captioned action), and upon actual knowledge with respect to themselves and their own acts, and upon information and belief as to all other matters, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement, trademark infringement, trade dress infringement, copyright infringement, and unfair competition under federal, state, and/or common law. Plaintiffs assert infringement of United States Patent No. 11,833,245 ("the '245 patent"), arising under the United States patent laws, Title 35, United States Code § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Defendants' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic Brimonidine Tartrate Ophthalmic Solution, 0.025% ("Defendants' generic brimonidine ophthalmic solution") prior to the expiration of the '245 patent. Plaintiffs also bring this action against Defendants because [redacted] Defendants designed their product packaging with full knowledge of Bausch's Lumify® eye drops and Bausch's rights in its eye logo and trade dresses, and with the intent of capitalizing on the goodwill associated with Bausch, its eye logo, and its trade dresses. Indeed, Defendants have prepared multiple iterations of their proposed packaging that imitate Bausch's eye logo and trade dresses. Defendants have submitted some of this packaging to the FDA for approval, and the FDA's final approval of Defendants' ANDA for their generic eye drops to be offered and sold in the infringing packaging could potentially take place as soon as February 16, 2024. Defendants intend to [redacted]. Indeed, Defendants [redacted]

[redacted]. Given Defendants' [redacted] Defendants' knowing and willful infringement of Bausch's eye logo and trade dresses through Defendants' use of a confusingly similar logo and packaging for identical eye drop products.

THE PARTIES

2. Plaintiff Bausch & Lomb, Inc. is a corporation organized and existing under the laws of New York with a place of business at 1400 N. Goodman St. Rochester, NY 14609. Bausch is the registered holder of approved New Drug Application ("NDA") No. 208144, which covers Lumify® ophthalmic solution/drops (brimonidine tartrate, 0.025%).

3. Plaintiff Bausch & Lomb Ireland Limited ("Bausch Ireland") is a company organized and existing under the laws of Ireland, having its registered office at 3013 Lake Drive, Citywest Business Park, Dublin, Ireland. Bausch Ireland exclusively licenses the '245 patent.

4. Plaintiff Eye Therapies, LLC ("Eye Therapies") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 26933 Camino De Estrella, 2nd Fl., Dana Point, California 92624. Eye Therapies is the owner of the '245 patent.

5. Upon information and belief, Slayback Pharma, LLC ("Slayback") is a Delaware limited liability company having a principal place of business at 301 Carnegie Center, Suite 303, Princeton, NJ 08540, within this judicial district.

6. Upon information and belief, Slayback Pharma India LLP ("Slayback India") is a limited liability partnership organized under the laws of India, having a principal place of business

at 310, 3rd Floor, Manjeera Trinity Corporate, JNTU - Hitech City Road, KPHB Phase 3, Kukutpally Hyderabad, Telangana 500072, India.

7. Upon information and belief, Slayback is the parent corporation of Slayback India, and the acts of Slayback complained of herein were done with the cooperation, participation and assistance of Slayback India.

8. Upon information and belief, Dr. Reddy's Laboratories S.A., ("DRL SA") is a corporation organized and existing under the laws of Switzerland, having a place of business at Elisabethenanlage 11, CH-4051 Basel, Switzerland.

9. Upon information and belief, Dr. Reddy's Laboratories, Inc. ("DRL Inc." and together with DRL SA, "DRL") is a New Jersey corporation having a principal place of business at 107 College Road East, Princeton, NJ 08540.

10. Upon information and belief, DRL Inc. is a wholly owned subsidiary of DRL SA and is controlled by DRL SA, and the acts of DRL Inc. complained herein were done with the cooperation, participation and assistance of DRL SA.

11. Upon information and belief, Slayback has transferred to DRL the ownership of Defendants' ANDA seeking approval to market Defendants' generic brimonidine ophthalmic solution and intends to market the product upon approval.

THE PATENTS IN SUIT

12. The U.S. Patent and Trademark Office ("PTO") issued the '245 patent on December 5, 2023. The '245 patent claims, *inter alia*, methods of reducing eye redness consisting of topically administering 0.025% brimonidine as the sole active ingredient into ocular tissue. Plaintiffs hold all substantial rights in the '245 patent and have the right to sue for infringement thereof. A copy of the '245 patent is attached hereto as Exhibit 1.

13. In the prosecution that led to the issuance of the '245 patent, on May 31, 2023, Eye Therapies submitted to the USPTO the Final Written Decision by Patent Trial and Appeal Board in IPR2022-00142 ("the FWD"), which held that the claims of a different patent, U.S. Patent No. 8,293,742, unpatentable. Eye Therapies cited the FWD on page 1 of an Information Disclosure Statement and, on the same day, submitted claim amendments that were further explained in the submitted Remarks. *See* Exhibit 2 at 52.

14. Subsequent to this disclosure and claim amendments, on June 12, 2023, the Examiner issued correspondence, where he certified that he considered the FWD and issued a Final Rejection, raising only issues under 35 U.S.C. § 112. *See* Exhibit 2 at 24-31.

15. On June 30, 2023, Eye Therapies further amended its claims and submitted remarks responsive to the Examiner's Final Rejection. *See* Exhibit 2 at 17-23. Then, on July 24, 2023, the Examiner allowed the case. *See* Exhibit 2 at 12. The issue fee was promptly paid on July 25, 2023, and the '245 patent finally issued on December 5, 2023. *See* Exhibit 2 at 1-2, 11.

16. Bausch is the holder of NDA No. 208144 for Lumify®, which the FDA approved on December 22, 2017. In conjunction with NDA No. 208144, the '245 patent will be submitted for listing in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

17. Brimonidine tartrate ophthalmic solution, 0.025%, is sold in the United States under the trademark Lumify®.

DEFENDANTS' INFRINGING ANDA SUBMISSION

18. Upon information and belief, Defendants filed or caused to be filed with the FDA ANDA No. 216361, under Section 505(j) of the Act and 21 U.S.C. § 355(j). Pursuant to Section

505(b) of the Act, ANDA No. 216361 was required to include copies of Defendants' proposed product labeling for FDA review and acceptance during the ANDA approval period.

19. Upon information and belief, Defendants' ANDA No. 216361 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of Defendants' generic brimonidine ophthalmic solution, to be offered and sold in infringing product packaging, intended to be a generic version of Lumify®.

20. On or about August 16, 2021, Plaintiffs received a letter from Slayback dated August 13, 2021, purporting to be a Notice of Paragraph IV Certification regarding ANDA No. 216361 ("Slayback's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95. Slayback's Notice Letter was addressed to Bausch and Eye Therapies.

21. Slayback's Notice Letter alleges that ANDA No. 216361 was submitted to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of generic brimonidine ophthalmic solution, intended to be generic versions of Lumify®.

22. Slayback's Notice Letter states that ANDA No. 216361 contains the "required bioavailability or bioequivalence data or information with respect to brimonidine tartrate ophthalmic solution, 0.025%," for generic brimonidine ophthalmic solution.

23. Upon information and belief, Slayback's actions related to ANDA No. 216361 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of Slayback India.

24. On or about August 9, 2023, Plaintiffs received a letter from DRL dated August 3, 2023, purporting to be a Notice of Paragraph IV Certification regarding ANDA No. 216361 ("DRL's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95. DRL's Notice Letter was addressed to Bausch and Eye Therapies.

25. DRL's Notice Letter alleges that ANDA No. 216361 was submitted to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of generic brimonidine ophthalmic solution, intended to be generic versions of Lumify®.

26. DRL's Notice Letter states that ANDA No. 216361 contains the "required bioavailability and/or bioequivalence data or information" for generic brimonidine ophthalmic solution.

27. Upon information and belief, DRL's actions related to ANDA No. 216361 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of DRL SA.

28. Upon information and belief, ANDA No. 216361 seeks approval of Defendants' generic brimonidine ophthalmic solution that is the same, or substantially the same, as Lumify®.

29. As a result of Slayback's Notice Letter and DRL's Notice Letter, Plaintiffs filed related Complaints against Slayback and DRL in this district. *See Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.*, Civil Action No. 21-16766; *Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.*, Civil Action No. 23-2454, consolidated into *In re Lumify*, Civil Action No. 21-16766 (RK) (RLS) (CONSOLIDATED) (the "Pending Litigation"). As a result of the Pending Litigation, the FDA issued a 30-month stay of regulatory approval during which the FDA will not issue final approval of Defendants' ANDA No. 216361. The FDA's 30-month stay expires on February 16, 2024.

30. Plaintiffs, DRL, and Slayback consented to DRL joining to Civil Action No. 21-16766, which was Ordered by this Court on December 2, 2022. *See* Civil Action No. 21-16766, ECF No. 61.

31. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding ANDA No. 216361 for the '245 patent ("'245 Patent Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 C.F.R. § 314.95.

32. Despite that Defendants have not yet sent a '245 Patent Notice Letter, Defendants' prior Notice Letters and the information contained therein, coupled with regulatory requirements, demonstrate Defendants' infringement of the '245 patent.

JURISDICTION AND VENUE

33. This Court has subject matter jurisdiction under 15 U.S.C. §§ 1121; 17 U.S.C. §§ 501 *et seq.*; and 28 U.S.C. §§ 1331, 1338(a) and (b), 2201, and 2202. *See also Cephalon Inc. v. Sandoz Inc.*, Civil Action No. 11-821, 2012 U.S. Dist. LEXIS 26494, at *15 (D. Del. Mar. 1, 2012) (finding that court had subject matter jurisdiction pursuant to 35 U.S.C. § 271(e)(2) and/or 25 U.S.C. § 1338(a) regardless of receipt of a later Paragraph IV certification, where the defendant had sent an original Paragraph IV certification putting the plaintiffs on notice of the infringing ANDA). Pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over Plaintiffs' state law claims because those claims are substantially related to Plaintiffs' federal claims.

34. Upon information and belief, this court has jurisdiction over Slayback. Upon information and belief, Slayback is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Slayback directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic brimonidine ophthalmic solution to be offered and sold in infringing product packaging. Upon information and belief, Slayback purposefully has conducted and continues to conduct business in this judicial district. Upon

information and belief, Slayback has its principal place of business at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540. Upon information and belief, Slayback has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

35. Upon information and belief, Slayback has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. Slayback's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs and offer and sell the infringing eye drops in the infringing product packaging. Upon information and belief, Slayback intends to direct sales of its drugs in the infringing product packaging into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Slayback will engage in marketing of Defendants' generic brimonidine ophthalmic solution to be offered and sold in infringing product packaging in New Jersey upon approval of Defendants' ANDA.

36. Upon information and belief, this court has jurisdiction over Slayback India. Upon information and belief, Slayback India is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Slayback India directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic brimonidine ophthalmic solution to be offered and sold in the infringing product packaging. Upon information and belief, Slayback India purposefully has conducted and continues to conduct business in this judicial district in concert with Slayback.

37. Upon information and belief, Slayback and Slayback India operate as interrelated corporate entities. Upon information and belief, Slayback is the parent corporation of Slayback India. Upon information and belief, Slayback and Slayback India each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

38. Upon information and belief, this court has jurisdiction over DRL Inc. Upon information and belief, DRL Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, DRL Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Defendants' generic brimonidine ophthalmic solution to be offered and sold in the infringing product packaging. Upon information and belief, DRL Inc. purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, DRL Inc. is a New Jersey corporation having a principal place of business at 107 College Road East, Princeton, NJ 08540. Upon information and belief, DRL Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

39. Upon information and belief, this court has jurisdiction over DRL SA. Upon information and belief, DRL SA is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, DRL SA directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial

district is a likely destination for Defendants' generic brimonidine ophthalmic solution to be offered and sold in infringing product packaging. Upon information and belief, DRL SA purposefully has conducted and continues to conduct business in this judicial district in concert with DRL Inc. and Slayback.

40. Upon information and belief, DRL operates as interrelated corporate entities. Upon information and belief, DRL Inc. is a wholly owned subsidiary of DRL SA and is controlled by DRL SA. Upon information and belief, DRL SA and DRL Inc. each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

41. Upon information and belief, DRL has taken the costly, significant step of seeking FDA approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New Jersey and elsewhere. DRL's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs in the infringing product packaging. Upon information and belief, DRL intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, DRL will engage in marketing of Defendants' generic brimonidine ophthalmic solution to be offered and sold in the infringing product packaging in New Jersey upon approval of Defendants' ANDA.

42. In a related matter, DRL agreed that it would not contest personal jurisdiction or venue in that action. *Bausch & Lomb, Inc. et al. v. Slayback Pharma LLC et al.*, Civil Action No. 21-16766, ECF No. 61.

43. Defendants know or should know that Lumify® is manufactured for Bausch, at least because that information is included in the label for Lumify® and is publicly available and because Defendants have been sued in *Bausch & Lomb, Inc., et al. v. Slayback Pharma LLC, et al.*, Civil Action No. 21-16766.

44. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

45. Venue is proper against Slayback Pharma, LLC, which maintains a regular and established place of business in this judicial district.

46. Venue is proper against Slayback India, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

47. Venue is proper against DRL Inc., which maintains a regular and established place of business in this judicial district.

48. Venue is proper against DRL SA, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

49. This Court also has personal jurisdiction over Defendants and venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) because Plaintiffs are being harmed in this district; Defendants are doing business in this district; and Defendants plan to offer and sell the infringing eye drops with the infringing logo and product packaging on products imported and/or shipped into this district, stored in this district, and sold from this district.

BAUSCH AND ITS LUMIFY® EYE DROPS

50. Bausch is a global eye health company that is dedicated to protecting and enhancing the gift of sight for millions of people around the world, from the moment of birth through every phase of life. Bausch's core businesses include over-the-counter eye health supplements, eye care

products, ophthalmic pharmaceuticals, contact lenses, lens care products, and ophthalmic surgical devices and instruments.

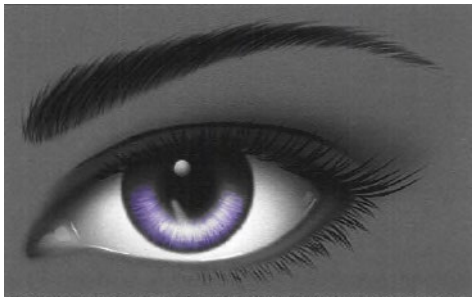
51. Founded in 1853, Bausch has a significant global research and development, manufacturing, and commercial footprint—with approximately 13,000 employees and a presence in nearly 100 countries.

52. Bausch has long been associated with significant advances in eye health and has stood at the forefront of cutting-edge scientific and technological optical advancements.

53. In 2018, Bausch began offering its Lumify® eye drops, the first and only over-the-counter eye drops formulated with low dose brimonidine tartrate 0.025% for the treatment of ocular redness.

Bausch's Distinctive Eye Logo and Trade Dresses for Its Lumify® Eye Drops

54. Since introducing the Lumify® eye drops in 2018, Bausch has continuously promoted and sold its product using the distinct logo shown below (the "Eye Logo"):



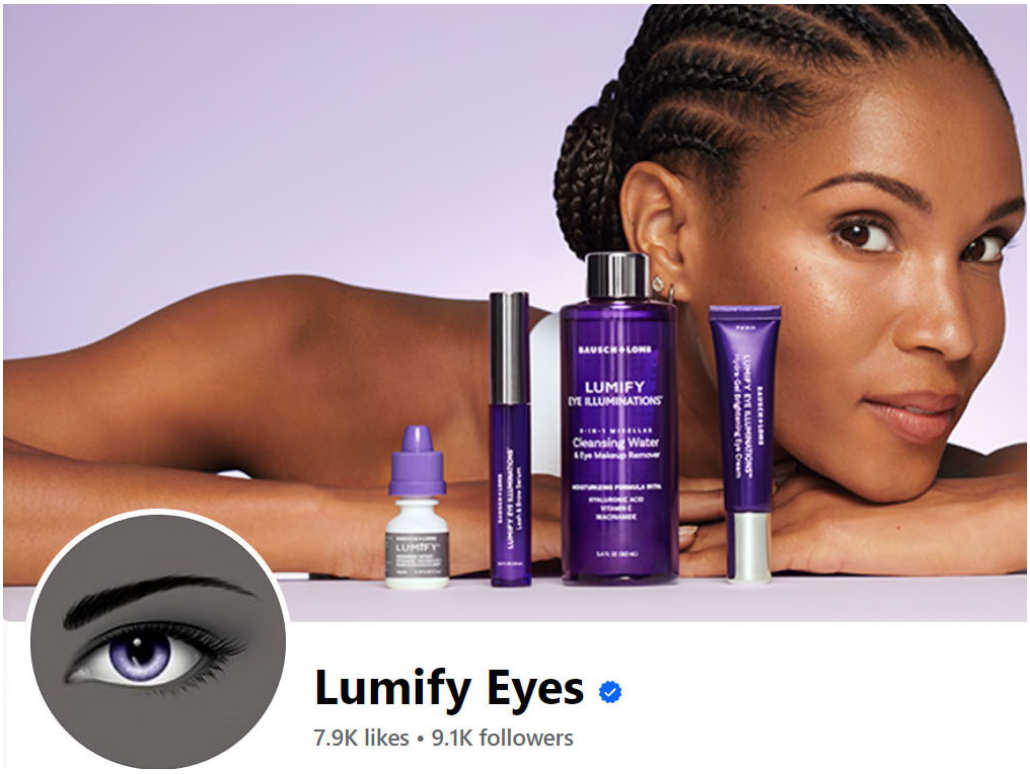
55. Bausch's Eye Logo is used and promoted in various ways, including on the packaging of all Lumify® branded eye drop products, on social media and other digital media, and in advertisements, including in-store promotions, to identify the source of Bausch's products, exposing myriad consumers to the logo prior to sale, at the point of sale, and post-sale, *e.g.*:

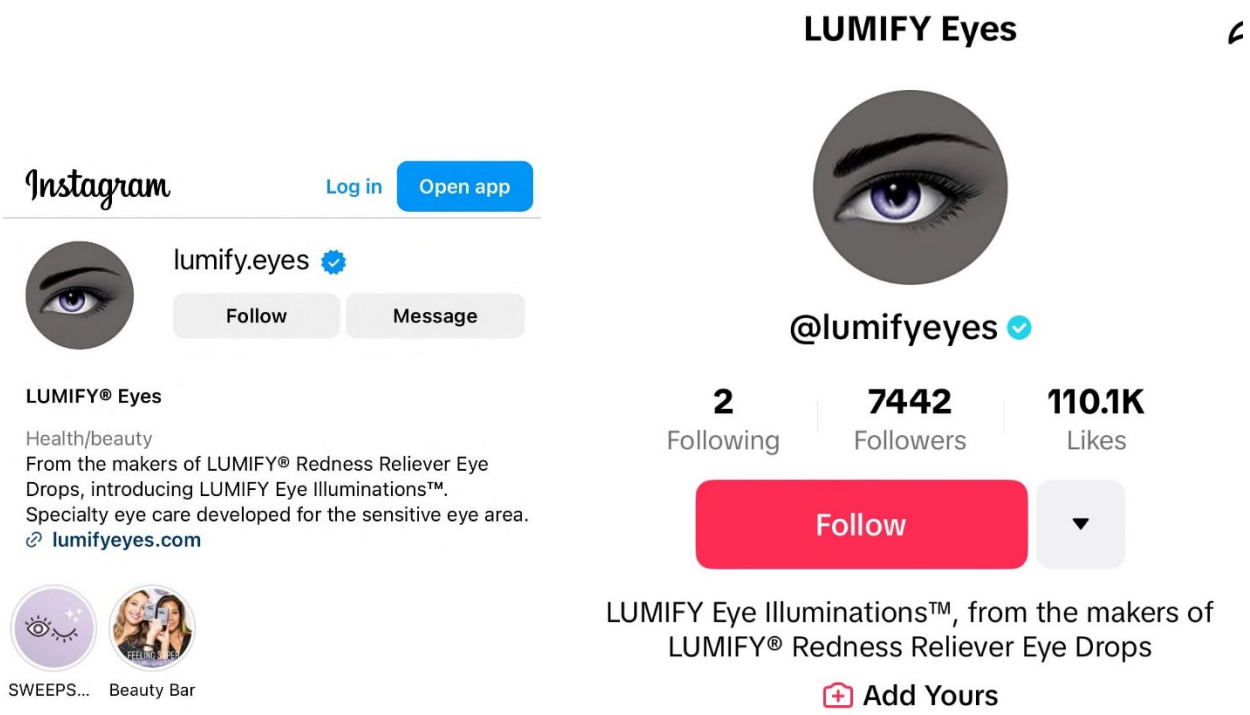

LUMIFY
LUMIFY
LUMIFY


BAUSCH+LOMB
NDC 24208-537-99
NEW PRODUCT
LUMIFY™
BRIMONIDINE TARTRATE
OPHTHALMIC SOLUTION 0.025%
REDNESS RELIEVER EYE DROPS
• Works in 1 minute
• Lasts up to 8 hours
Sterile 0.08 FL OZ (2.5 mL)


LUMIFY
LUMIFY
Systane ZADITOR
NAPHCON A
Opcon-A


MULTI-PACK
LUMIFY®
BRIMONIDINE TARTRATE OPHTHALMIC SOLUTION 0.025%
REDNESS RELIEVER EYE DROPS
MULTI-PACK
BAUSCH+LOMB
LUMIFY
FDA
Works in 1 minute
Lasts up to 8 hours
BAUSCH+LOMB
TWO 0.25 FL OZ (7.5 mL) BOTTLES


BAUSCH+LOMB
LUMIFY
EYE ILLUMINATIONS
Cleansing Water
& Eye Makeup Remover
Lumify Eyes
7.9K likes • 9.1K followers



56. The Eye Logo plays an important part in the overall look and feel of Bausch's Lumify® eye drop packaging. Since the inception of its Lumify® eye drops, Bausch has extensively used and promoted a packaging design with the Eye Logo to ensure consistent branding and to distinguish its products from others in the marketplace. This packaging design includes the features disclosed below, the combination of which creates a distinctive trade dress that has come to be uniquely associated with Bausch's Lumify® brand ("Eye Logo Trade Dress"):

- Design of an eyebrow in black and an eye in white, black, and purple, positioned in the top third of the product packaging
- Displayed on a gray background.

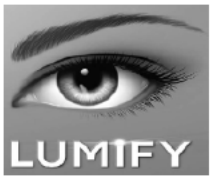
57. Since the inception of its Lumify® eye drops, Bausch has also extensively used and promoted an overall packaging design with a distinct and uniform look and feel to ensure consistent branding and to distinguish its products from others in the marketplace.

58. The overall appearance of the Lumify® eye drops packaging design includes the features disclosed below, the combination of which creates a distinctive trade dress that has come to be uniquely associated with Bausch's Lumify® brand ("Lumify® Packaging Trade Dress"):

- Design of an eyebrow in black and an eye in white, black, and purple, positioned in the top third of the product packaging, followed by
- "BRIMONIDINE TARTRATE OPTHALMIC SOLUTION 0.025%," followed by
- "REDNESS RELIEVER EYE DROPS," followed by
- Two purple bullet points with the stylized wording "Works in 1 minute" and "Lasts up to 8 hours" in white
- All displayed on a gray background.

59. The Eye Logo, the Eye Logo Trade Dress, and the Lumify® Packaging Trade Dress are central to the Lumify brand identity. Bausch uses the Eye Logo, the Eye Logo Trade Dress, and the Lumify® Packaging Trade Dress in connection with the promotion and sale of its Lumify® eye drops and has developed strong common law rights, consumer recognition, and brand identity in the Eye Logo, the Eye Logo Trade Dress, and the Lumify® Packaging Trade Dress from their consistent, exclusive, and extensive use in commerce.

60. In addition to its strong common law rights, Bausch owns the following valid and subsisting U.S. trademark registrations for the Eye Logo, the Eye Logo Trade Dress, and the Lumify® Packaging Trade Dress:

Mark	Goods	App No./ Reg. No.	First-Use Date	Filing Date/ Reg. Date
	Ophthalmic preparations and eye drops	97453457 7186633	05/07/2018	06/10/2022 10/10/2023
	Eye drops	97453458 7179843	05/07/2018	06/10/2022 10/03/2023
	Ophthalmic preparations and eye drops	97920512 7236575	05/07/2018	05/04/2023 12/05/2023

Mark	Goods	App No./ Reg. No.	First-Use Date	Filing Date/ Reg. Date
	Ophthalmic preparations and eye drops	97453460 7192472	05/07/2018	06/10/2022 10/17/2023

61. Bausch also owns valid and subsisting U.S. Copyright Registration No. VA0002355792, registered June 1, 2023 (the "Bausch Copyright"), for its Eye Logo.

Sales and Advertising of Bausch's Lumify® Eye Drops

62. Bausch's Lumify® eye drops are promoted, offered, and sold nationwide in the eye care section of most major retailers, such as Target, Walmart, CVS, Walgreens, Costco, Sam's Club, Rite Aid, Vons, Albertsons, and Safeway, including at locations in this judicial district. Bausch's Lumify® eye drops are also offered for sale and sold through Bausch's own website as well as through the websites and/or apps of major retailers.

63. Bausch's Lumify® eye drops have enjoyed considerable commercial success across the United States. For example, Bausch's Lumify® eye drops accounted for $131 million of Bausch's revenue in 2022 alone.

64. Bausch's Lumify® eye drops are the number one eye doctor recommended redness reliever eye drop brand, receiving approximately 90% of doctors' recommendations. Before the launch of Bausch's Lumify® eye drops, less than 10% of eye care professionals recommended any kind of redness relievers to their patients and most advised against using any redness relievers.

Since the launch of Bausch's Lumify® eye drops, 76% of such eye care professionals recommend redness relievers and 92% of such professionals recommend Bausch's Lumify® eye drops.

65. Bausch devotes substantial time, effort, and resources annually to advertising, marketing, and promoting its Lumify® brand and products—including its Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress—through virtually every type of digital and print media advertisements; *e.g.*, Internet advertising, social media profiles and campaigns, sponsorships, linear and connection TB, and retail media. For example, Bausch invested significant resources launching a "LUMIFY eye dance" challenge campaign on TikTok that generated over [redacted] views during the month-long duration of the campaign.

66. As of October 2023, Bausch's Lumify® brand has garnered over [redacted] media impressions in 2023, consisting of unpaid endorsements from media, make-up artists, celebrities, and beauty influencers.

67. In addition to its own advertising and promotional activities, Bausch's Lumify® brand and products receive significant unsolicited media coverage, attention, and praise.

68. Bausch's Lumify® eye drops also receive numerous positive reviews in various print and online media, including from singer Jennifer Lopez, actress Brooke Shields, actress Christine Quinn, fashion model Naomi Campbell, actress Jessica Alba, fashion model Winnie Harlow, and celebrity make-up artist Vincent Oquendo, among many others. Bausch's Lumify® eye drops have a 95% satisfaction rating.

69. Bausch has also received significant media attention and numerous accolades for its Lumify® eye drops, including but not limited to, the following awards and recognitions:

- The Zoe Report's Best Affordable Beauty Winner, 2018
- New You's The Eyes Have It, 2018

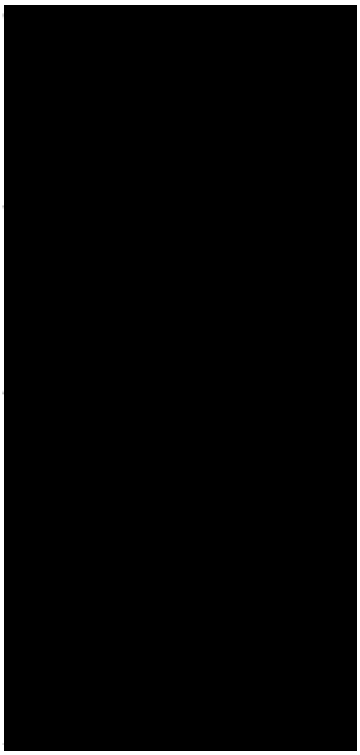
- NACDS' Product of the Year, 2018
- Bride's The Best of Beauty (Eyes), 2019
- New Beauty's Best Innovations, 2019
- National Association of Chain Drug Stores' Total Store Exp, Product Showcase Winner, 2019
- Muse Creative, Social Media Campaign Award and Product or Service Branding Award, 2019
- U.S. Bases, Top 25 Breakthrough Innovations List, 2020
- Into the Gloss's Top 25: Cheap Thrills, 2021
- Glamour's Best Beauty Innovator Award, 2022
- New Beauty Magazine Beauty Awards "Never Knew We Needed", 2022
- CNET's Best Over the Counter Eye Drops, 2023
- Forbes' Best Eye Drops for Red Eyes, According to Experts, 2023
- New Beauty's "Best Brightening Eye Drops", 2023

70. As a result of the Eye Logo's, the Eye Logo Trade Dress's, and the Lumify® Packaging Trade Dress's distinctive nature and inherent strength, widespread use, advertising, publicity, promotion, and substantial sales, the logos and trade dresses have been strong and well-known since long before Defendants began their unlawful acts. The Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress serve as succinct symbols of Bausch's Lumify® eye drops and their high quality and effectiveness in treating ocular redness.

DEFENDANTS' WRONGFUL ACTS

71. During discovery in the Pending Litigation, Defendants produced to Plaintiffs an iteration of proposed labeling submitted for FDA approval in or around March 2022 in connection

with ANDA No. 216361. The proposed labeling was intended to be used for Defendants' infringing eye drops, and included the following proposed packaging (the "First Infringing Packaging"):



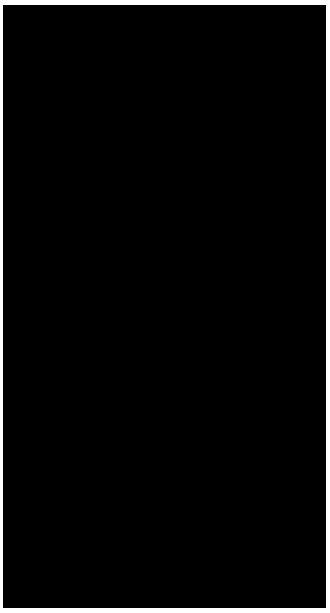
72. The FDA notified Defendants in a letter dated January 3, 2023, that ANDA No. 216361 was tentatively approved based on the information presented therein, including the First Infringing Packaging (the "Tentative Approval Letter").

73. The FDA's Tentative Approval Letter informed Defendants that a request for final approval containing no new information or other changes to the ANDA generally requires a period of three months for agency review, and that any subsequent changes to ANDA No. 216361, including changes to Defendants' Infringing Packaging, may delay the FDA's final approval of ANDA No. 216361.

74.

[redacted]

75. In December 2023, Defendants produced to Plaintiffs in the Pending Litigation a different version of proposed labeling, shown below ("Second Infringing Packaging," together with the First Infringing Packaging, the "Infringing Packaging"), [redacted]



76. The Infringing Packaging prominently displays logos that are confusingly similar to Bausch's Eye Logo. The Infringing Packaging [redacted] Like Bausch's Eye Logo Trade Dress, [redacted] And, like the Lumify® Packaging Trade Dress, [redacted]

[redacted]

77. During the course of the Pending Litigation, Defendants agreed to provide Plaintiffs [redacted]

78. Upon information and belief, Defendants [redacted] using the Infringing Packaging that displays a logo confusingly similar to Bausch's Eye Logo and in packaging that mimics the Eye Logo Trade Dress and the Lumify® Packaging Trade Dress.

79. Upon information and belief, the infringing eye drops offered for sale and sold in the Infringing Packaging will be offered for sale by many of the same retailers that offer, promote, and sell Bausch's Lumify® eye drops.

INJURY TO THE PUBLIC AND BAUSCH

80. Defendants' unauthorized uses of Bausch's Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress are likely to cause confusion, mistake, and/or deception as to the source or origin of Defendants' products, and are likely to falsely suggest a sponsorship, connection, or association between Defendants, their products, and/or their commercial activities with Bausch and/or its Eye Logo, Eye Logo Trade Dress, and/or Lumify® Packaging Trade Dress.

81. Defendants' imminent, unauthorized uses of the Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress have and/or will damage and irreparably injure, and if permitted to continue, will further damage and irreparably injure, Bausch, its Eye Logo, Eye Logo Trade Dress, and/or Lumify® Packaging Trade Dress; its reputation and goodwill; and/or the public's interest in being free from confusion, mistake, and/or deception. Bausch has invested

significant resources in developing its Lumify® brand identity, including the Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress, and is committed to protecting this identity to ensure consumers of health care products can purchase Bausch's market-leading eye drops with confidence.

82. Bausch has no control over the nature and quality of Defendants' infringing eye drops, and Defendants' sales of such infringing eye drops will irreparably damage Bausch's reputation and goodwill in its products and rights.

83. Defendants know that their uses of the Eye Logo, Eye Logo Trade Dress, and/or Lumify® Packaging Trade Dress are neither permitted nor authorized. As a result, Defendants have acted knowingly, willfully, in reckless disregard of Bausch's rights, and in bad faith.

COUNT I FOR PATENT INFRINGEMENT
Infringement of the '245 Patent Under § 271(e)(2)

84. Paragraphs 1-83 are incorporated herein as set forth above.

85. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '245 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216361 seeking approval for the commercial marketing of Defendants' generic brimonidine ophthalmic solution before the expiration date of the '245 patent.

86. Upon information and belief, Defendants' generic brimonidine ophthalmic solution will, if approved and marketed, infringe at least one claim of the '245 patent.

87. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Defendants' generic brimonidine ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '245 patent.

88. If Defendants' marketing and sale of Defendants' generic brimonidine ophthalmic solution prior to the expiration of the '245 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT
Declaratory Judgment of Infringement of the '245 Patent

89. Paragraphs 1-88 are incorporated herein as set forth above.

90. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

91. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

92. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Defendants' generic brimonidine ophthalmic solution before the expiration date of the '245 patent, including the filing of ANDA No. 216361.

93. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' generic brimonidine ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '245 patent.

94. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Defendants' generic brimonidine ophthalmic solution will constitute infringement of at least one claim of the '245 patent.

COUNT III FOR TRADEMARK INFRINGEMENT AND TRADE DRESS INFRINGEMENT
Under Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1)

95. Paragraphs 1-94 are incorporated herein as set forth above.

96. Without Bausch's consent, Defendants have used, without authorization, reproductions, copies, and colorable imitations of Bausch's registered Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress in their regulatory filings and have imminent plans to use such reproductions, copies, and colorable imitations in connection with the offering, distribution, and advertising of ophthalmic preparations and eye drops, which is likely to cause confusion, or to cause mistake, or to deceive, in violation of Section 32(1)(a) of the Lanham Act, 15 U.S.C. § 1114(1)(a).

97. Without Bausch's consent, Defendants have reproduced, copied, or colorably imitated Bausch's Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress and applied such reproductions, copies, and/or colorable imitations to labels, signs, prints, packages, wrappers, receptacles, or advertisements that are intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising of ophthalmic preparations and eye drops, which is likely to cause confusion, or to cause mistake, or to deceive, in violation of Section 32(1)(b) of the Lanham Act, 15 U.S.C. § 1114(1)(b).

COUNT IV FOR TRADEMARK INFRINGEMENT, TRADE DRESS INFRINGEMENT, FALSE DESIGNATION OF ORIGIN, PASSING OFF, AND UNFAIR COMPETITION
Under Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A)

98. Paragraphs 1-97 are incorporated herein as set forth above.

99. Bausch's Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress are and have been distinctive since before Defendants' use of marks and trade dresses confusingly similar to the Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress, based on, among other things, their inherent distinctiveness and extensive nationwide use, promotion, marketplace success, and/or recognition.

100. Defendants' uses of the Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress, as described above, are likely to cause confusion, or to cause mistake, or to deceive as to the origin, sponsorship, or approval of Defendants, their products, and/or their commercial activities by or with Bausch, and thus constitutes trademark infringement, trade dress infringement, false designation of origin, passing off, and/or unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

COUNT V FOR TRADEMARK INFRINGEMENT, TRADE DRESS, AND UNFAIR COMPETITION
Under N.J.S.A. § 56:4-1

101. Paragraphs 1-100 are incorporated herein as set forth above.

102. Defendants' activities, described above, constitute the misappropriation for Defendants' own use of Bausch's name, brand, trademarks, trade dresses, reputation, and/or goodwill in violation of the laws of the State of New Jersey, N.J.S.A. § 56:4-1.

COUNT VI FOR TRADEMARK INFRINGEMENT AND TRADE DRESS INFRINGEMENT
Under N.J.S.A. § 56:3-13.16(a)

103. Paragraphs 1-102 are incorporated herein as set forth above.

104. Defendants' activities, described above, constitute uses without Bausch's consent of reproductions, copies, or colorable imitations of Bausch's Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress in connection with Defendants' sale, distribution, offering for sale, and advertising in New Jersey of goods or services that is likely to cause confusion or mistake or to deceive as to the source of origin of the goods or services, in violation of the laws of the State of New Jersey, N.J.S.A. § 56:3-13.16(a).

COUNT VII FOR TRADEMARK INFRINGEMENT, TRADE DRESS INFRINGEMENT, UNFAIR COMPETITION, FALSE DESIGNATION OF ORIGIN, AND MISAPPROPRIATION
Under New Jersey Common Law

105. Paragraphs 1-104 are incorporated herein as set forth above.

106. Defendant's activities, described above, are likely to cause confusion, mistake, or deception as to the origin, sponsorship, or approval of Defendants, their products, and/or their commercial activities by or with Bausch, and thus constitute common-law trademark infringement, unfair competition, false designation of origin, and/or misappropriation of the Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress and goodwill under New Jersey common law.

COUNT VIII FOR COPYRIGHT INFRINGEMENT
Under 17 U.S.C. § 106

107. Paragraphs 1-106 are incorporated herein as set forth above.

108. The Eye Logo is an original work of authorship subject to copyright protection under 17 U.S.C. § 101 *et seq.*

109. Bausch owns the Bausch Copyright for the Eye Logo.

110. Defendants had access to the Eye Logo and copied it without authorization.

111. Defendants' Infringing Packaging includes a logo is at least substantially similar, if not virtually identical to, the Eye Logo.

112. Defendants violated Bausch's exclusive copyright in the Bausch Copyright by reproducing, creating unauthorized derivative works, publicly displaying, and/or distributing it without authorization.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '245 patent by submitting or causing to be submitted ANDA No. 216361 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Defendants' generic brimonidine ophthalmic solution before the expiration of the '245 patent;

2. Order that the effective date of any approval by the FDA of Defendants' generic brimonidine ophthalmic solution be a date that is not earlier than the expiration of the '245 patent, or such later date as the Court may determine;

3. Enjoin Defendants from the commercial manufacture, use, import, offer for sale, and/or sale of Defendants' generic brimonidine ophthalmic solution until expiration of the '245 patent, or such later date as the Court may determine;

4. Enjoin Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of Defendants' ANDA No. 216361 until expiration of the '245 patent;

5. Declare that Defendants' uses of the Eye Logo, Eye Logo Trade Dress, and Lumify® Packaging Trade Dress infringe Bausch's rights in those marks/designs/trade dresses and constitute trademark infringement, trade dress infringement, copyright infringement, and/or unfair competition under federal and/or state law, as detailed above;

6. Enjoin Defendants and their employees, agents, partners, officers, directors, owners, shareholders, principals, subsidiaries, related companies, affiliates, distributors, dealers, and all persons in active concert or participation with any of them:

a. From using or registering the Eye Logo, Eye Logo Trade Dress, Lumify® Packaging Trade Dress and/or any other marks, logos, trade dresses, or

designs that are confusingly or substantially similar to the Eye Logo, Eye Logo Trade Dress, or Lumify® Packaging Trade Dress;

b. From representing by any means whatsoever, directly or indirectly, that any products offered by Defendants, or any activities undertaken by Defendants, are associated or connected in any way with Bausch or sponsored or authorized by or affiliated with Bausch;

7. Direct Defendants to, within thirty (30) days after the entry of the injunction, file with this Court and serve on Bausch's attorneys a report in writing and under oath setting forth in detail the manner and form in which Defendants have complied with the injunction;

8. Direct Defendants to immediately destroy all products, advertisements, packaging, promotional materials, stationery, forms, and/or any other materials and things that contain or bear the Eye Logo, Eye Logo Trade Dress, Lumify® Packaging Trade Dress, and/or any other marks, logos, trade dresses, or designs that are confusingly or substantially similar to the Eye Logo, Eye Logo Trade Dress, or Lumify® Packaging Trade Dress;

9. Direct Defendants to immediately destroy all products, advertisements, packaging, promotional materials, stationery, forms, and/or any other materials and things that contain or bear the Bausch Copyright and/or any other works that are substantially similar to the Bausch Copyright;

10. Declare this to be an exceptional case under 35 U.S.C. §§ 285, 271(e)(4), and 15 U.S.C. § 1117(a), and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

11. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: December 18, 2023
Newark, New Jersey

s/ William P. Deni, Jr.
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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: December 18, 2023
Newark, New Jersey

s/ William P. Deni, Jr.

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